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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/508,977 03/17/00 KIY

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HM22/0702

EXAMINER

MARX, I

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

07/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/508,977

Applicant(s)

Kiy

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 20) ☐ Other:

The application should be reviewed for errors and conformity with domestic practice.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation of "ciliates (protozoa)". It is unclear what is intended by the parenthetical term. In addition, the nature of the process intended is not clearly set forth. The preamble is directed to "a fermentation process". Yet the process fails to disclose clearly delineated process steps. It is recommended that the claims be amended to recite process steps in logical order, i.e., cultivation, production of biomass and extraction of a specific product. The phrase "biogenous valuable substances" is confusing. The products intended are uncertain. Also, the term "valuable" is ambiguous and open to interpretation.

In claims 2 and 14 the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In claims 5 and 9 the phrases "for example" and "preferably" render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

In claim 2, the meaning of "wild strains" is uncertain. Are wild-type strains intended?

In claims 5 and 12-13 the parenthetical phrases render the claim indefinite because it is unclear whether the limitation(s) in parenthesis are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 12 fails to find proper antecedent basis in claim 1 for "the cells contained in the cell extract".

Claim 13 fails to find proper antecedent basis in claim 1 for "the cell extraction rate or dilution rate".

Claim 10 encompasses an improper Markush grouping because of the absence of "and" or "or". Claim 14 encompasses an improper Markush grouping because it recites more than one "and". Also, it is unclear whether "biomass" forms part of the Markush listing, because of "or else". The claims as drafted do not follow the correct form (e.g. selected from the group consisting of A,B, AND C). See MPEP 2173.05(h)(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Kiy *et al.*

Kiy *et al.* disclose the continuous cultivation of ciliates in a complex medium for the production of a biological product in a stirred fermentor at conventional temperature and pH. See, e.g., col. 5, lines 15-24. With respect to the medium containing killed biomass of feed

organisms, it is noted that during the culturing process, many microorganism cells naturally die off and serve as nutrients to the survivors.

Claims 1-5, 7, 10-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tiedke *et al.*.

Tiedke *et al.* disclose the continuous cultivation of ciliates in a complex medium for the production of a biological product in a fermentor at conventional temperature and pH. See, e.g., col. 1, lines 45-50. With respect to the medium containing killed biomass of feed organisms, it is noted that during the culturing process, many microorganism cells naturally die off and serve as nutrients to the survivors.

Claims 1-5, 7, 10-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiy *et al.* (1991).

Kiy *et al.* disclose the continuous cultivation of ciliates in a complex medium for the production of a biological product in a bubble column reactor at conventional temperature and pH. See, e.g., page 16, col. 1. With respect to the medium containing killed biomass of feed organisms, it is noted that during the culturing process, many microorganism cells naturally die off and serve as nutrients to the survivors.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiy *et al.* taken with Curds *et al.* and Stafford (In Demain *et al.*, Industrial Microbiology and Biotechnology, 1986, ASM).

As noted in the anticipation rejection, *supra*, Kiy *et al.* disclose the continuous cultivation of ciliates in a complex medium for the production of a biological product in a stirred fermentor at conventional temperature and pH. See, e.g., col. 5, lines 15-24. With respect to the medium containing killed biomass of feed organisms, it is noted that during the culturing process, many microorganism cells naturally die off and serve as nutrients to the survivors. In addition Curds *et al.* teach the cultivation of ciliates using biomass of feed organisms (See, e.g., page 348).

The reference differs from the claimed invention in that the rate of the operating volume of the fermentor is not disclosed. However, Stafford *et al.* adequately demonstrate that continuous

processes are well known in the art and are adapted to various fermentation processes by known methodology to optimize the productivity of the respective cultures. See, e.g., pages 144-145.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Kiy *et al.* for the continuous cultivation of ciliates for the production of biological products such as enzymes by culturing the cells at a specific operating volume for the expected benefit of maximizing the production of valuable biological molecules, such as useful enzymes.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiedke *et al.* taken with Curds *et al.*, Kiy *et al.* (1991) and Stafford (In Demain *et al.*, Industrial Microbiology and Biotechnology, 1986, ASM).

As noted in the anticipation rejection, *supra*, Tiedke *et al.* disclose the continuous cultivation of ciliates in a complex medium for the production of a biological product in a stirred fermentor at conventional temperature and pH. See, e.g., col. 1, lines 45-50. With respect to the medium containing killed biomass of feed organisms, it is noted that during the culturing process, many microorganism cells naturally die off and serve as nutrients to the survivors. In addition Curds *et al.* teach the cultivation of ciliates using biomass of feed organisms (See, e.g., page 348). Moreover, Kiy *et al.* also teach the continuous cultivation of ciliates in a complex medium for the production of a biological product in a stirred fermentor at conventional temperature and pH. See, e.g., page 16.

The Tiedke and Kiy references differ from the claimed invention in that the rate of the operating volume of the fermentor is not disclosed. However, Stafford *et al.* adequately demonstrate that continuous processes are well known in the art and are adapted to various fermentation processes by known methodology to optimize the productivity of the respective cultures. See, e.g., pages 144-145. In addition, Kiy *et al.* disclose suitable concentrations of nutrients for the process, which appear to correspond to the claimed amounts. See, e.g., page 14, col. 1. In any event, the optimization of conditions identified as result-effective variables cited in the references such as the concentration of nutrients and the provision of growth factors are the

essence of biotechnical engineering and would have been prima facie obvious to a person having ordinary skill in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Tiedke *et al.* and Kiy *et al.* for the continuous cultivation of ciliates for the production of biological products such as enzymes by culturing the cells at specific concentrations of nutrients and operating volumes of the culture media for the expected benefit of maximizing the production of valuable biological molecules, such as useful enzymes.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .



Irene Marx
Primary Examiner
Art Unit 1651